SAFETY DATA SHEETS

This SDS packet was issued with item: 078947246

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078947245 078947247 078947248 078947249 078947250



1. IDENTIFICATION

Product Name Recommended use of the chemical and restrictions on use Identified uses

Restrictions on Use Company Identification

Customer Information Number Emergency Telephone Number CHEMTREC Number Other Emergency Number: MOVODYL[™] Chewable Tablets (carprofen)

Veterinary product used as a non-steroidal, antiinflammatory drug (nsaid) for dogs only. Not for human use. Do not use in cats. Virbac AH, Inc. P.O. Box 162059 Fort Worth, Texas 76161 (800) 338-3659

(800) 424-9300 Human Toll-free 833-224-2009 Animal Toll-free 833-224-2013 April 14, 2022 New document

Issue Date

Supersedes Date

Safety Data Sheet prepared in accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

2. HAZARD IDENTIFICATION

Hazard Classification

Skin Sensitization – Category 1B Reproductive toxicity (the unborn child) - Category 2 Specific target organ toxicity (Repeat Exposure) – Category 2 (digestive system)

Label Elements

Hazard Symbols



Signal Word: Warning

Hazard Statements

May cause an allergic skin reaction. Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. (ingestion)

Precautionary Statements

Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

Do not breathe dusts.

Contaminated work clothing must not be allowed out of the workplace.

Wear protective gloves/protective clothing/face protection.

Wash hands thoroughly with soap and water after handling.

Wear protective gloves/protective clothing/eye protection/face protection.



2. HAZARD IDENTIFICATION

Response

If exposed or concerned: Get medical advice/attention. If on skin: Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Storage

Stoke locked up.

Disposal

Dispose of contents/container in accordance with local, regional, national and international regulations.

Other Hazards

None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms:

This product is a mixture.

| Component Name | CAS Number | Concentration |
|-------------------------|------------|---------------|
| Carprofen | 53716-49-7 | *** |
| Sodium Starch Glycolate | 9063-38-1 | * |
| Stearic Acid | 57-11-4 | * |
| Lactose Monohydrate | 10039-26-6 | * |

Composition comments *** 25, 37.5, 50, 75, or 100 mg per tablet

* Designates that the specific chemical identify and/or percentage of composition has been withheld as a trade secret. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST - AID MEASURES

Description of necessary first-aid measures

Inhalation

Remove person to fresh air. Seek medical attention if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

Eyes

Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Get medical attention if irritation develops and persists.

Skin

Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.

Ingestion

Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions



4. FIRST - AID MEASURES

Most important symptoms/effects, acute and delayed

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort.

Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash.

If swallowed: Nausea, vomiting. Abdominal pain.

Chronic exposure to this material may cause serious gastrointestinal toxicity such as bleeding, ulceration, and perforation.

Indication of immediate medical attention and special treatment needed Notes to Physicians

Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

General Information

For personal protection, see section 8 of the SDS. If exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.

5. FIRE - FIGHTING MEASURES

Extinguishing Media

Water spray. Foam. Powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Unusual Fire and Explosion Hazards

During fire, gases hazardous to health may be formed.

Protective Equipment for Fire-Fighting

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Firefighting equipment/instructions

Use water spray to cool unopened containers

Specific methods hazards

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.



6. ACCIDENTAL RELEASE MEASURES

Environmental Precautions

Avoid discharge into drains, water courses or onto the ground.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Remove sources of ignition. Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

7. HANDLING AND STORAGE

Precautions for safe handling

Do not taste or swallow. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment..

Conditions for safe storage

Store in a well-ventilated place. Keep away from heat and sources of ignition. Store in original tightly closed container. @ 15-30°C (59-86°F). Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children. Protect from moisture.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational exposure limits: The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

| Components | Туре | Value |
|-------------------------------|------|------------|
| Carprofen (CAS 53716-16-49-7) | TWA | 1000 µg/m3 |

| US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) | | | | | |
|---|------|----------|---------------------|--|--|
| Components | Туре | Value | Form | | |
| Sodium Starch Glycolate (CAS 9063-38-18) | PEL | 5 mg/m3 | Respirable fraction | | |
| | | 15 mg/m3 | Total dust | | |
| Lactose Monohydrate (CAS 10039-26-6) | PEL | 5 mg/m3 | Respirable fraction | | |
| | | 15 mg/m3 | Total dust | | |
| US. ACGIH Threshold Limit Values | | | | | |
| Components | Туре | Value | | | |
| Sodium Starch Glycolate (CAS 9063-38-18) | TWA | 10 mg/m3 | | | |
| Stearic Acid (CAS 57-11-4) | TWA | 10 mg/m3 | | | |
| Lactose Monohydrate (CAS 10039-26-6) | TWA | 10 mg/m3 | | | |



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

US NIOSH: Pocket Guide to Chemical Hazards

| Component | Туре | Value | Form |
|--|------|----------|---------------------|
| Sodium Starch Glycolate (CAS 9063-38-18) | TWA | 5 mg/m3 | Respirable fraction |
| | | 10 mg/m3 | Total dust |
| Lactose Monohydrate (CAS 10039-26-6) | TWA | 5 mg/m3 | Respirable fraction |
| | | 10 mg/m3 | Total dust |
| Diele vie el livrit velve e | | 10 mg/m3 | Total dust |

Biological limit values

No biological exposure limits noted for the ingredients.

Control banding approach

Not available

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used and is normally adequate. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures

Respiratory Protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Skin/Hand Protection

Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations

Eye/Face Protection

If contact is likely, safety glasses with side shields are recommended.

Body Protection

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Thermal hazards

Not applicable

General hygiene considerations

Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Contaminated work clothing should not be allowed out of the workplace.

9. PHYSICAL AND CHEMICAL PROPERTIES

| Appearance | Tablet (chewable tablet) |
|----------------|--------------------------|
| Physical State | Solid |
| Form | Solid |
| Color | Light brown |
| Odor | Not available |
| Odor Threshold | Not available |
| рН | Not available |



9. PHYSICAL AND CHEMICAL PROPERTIES

| Density Boiling Range/Point (°C/F) Melting Point (°C/F) Flash Point (PMCC) (°C/F) Vapor Pressure Evaporation Rate (BuAc=1) Solubility in Water Vapor Density (Air = 1) Partition coefficient (n- octanol/water) Viscosity Auto-ignition Temperature Decomposition Temperature | Not available Not available Not available Not available Not available Not available Not available Not available Not available Not available |
|---|--|
| Upper explosive limit | Not available |
| Lower explosive limit | Not available |
| Flammability (solid, gas) | Not available |
| Other information Explosive properties Oxidizing properties | Not explosive Not oxidizing |

10. STABILITY AND REACTIVITY

Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical Stability

Material is stable under normal conditions..

Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

Conditions to Avoid

Contact with incompatible materials. Heat, flames and sparks. Moisture.

Incompatible Materials

Strong oxidizing agents. Acids.

Hazardous Decomposition Products

Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation: Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact: Prolonged skin contact may cause temporary irritation. There have been anecdotal reports that workers handling this material have experienced skin irritation and/or sensitivity reactions.

Carprofen

Species: Rabbit Severity: Non-irritating



11. TOXICOLOGICAL INFORMATION

Eye contact: Direct contact with eyes may cause temporary irritation

Carprofen Species: Rabbit Severity: Non-irritating

Ingestion: May be harmful if swallowed; however, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort.

Mild skin irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause an allergic skin reaction. Dermatitis. Rash.

If swallowed: Nausea, vomiting. Abdominal pain. Chronic exposure to this material may cause serious gastrointestinal toxicity such as bleeding, ulceration, and perforation.

Information on toxicological effects

| Acute toxicity: | May be harmful if swallowed. | | |
|---|------------------------------|---|--|
| Product Carprofen Chewable Tablets <u>Acute</u> | Species | Test Results | |
| Oral ATE | | 4545 mg/kg | |
| Components Carprofen (CAS 53716-49-7) | Species | Test Results | |
| <u>Acute</u> Intraperitoneal | | | |
| LD ₅₀ | Rat | 140 - 110 mg/kg (M/F) | |
| Oral LD ₅₀ | Mouse Rat | 282 mg/kg 149 mg/kg | |
| Subcutaneous | Nat | 143 mg/kg | |
| LD ₅₀ <u>Chronic</u> | Rat | 230 - 190 mg/kg (M/F) | |
| Oral | | | |
| NOAEL | Dog | 25 mg/kg/day, 2 years (Not carcinogenic; No effects at maximum dose) | |



| TOXICOLOGICAL INFORMATION | | |
|---|--------------------|--|
| | Rat | 10 mg/kg/day, 2 years (Not carcinogenic, Gastrointestinal system effects) |
| <u>Subchronic</u> Oral | | |
| NOAEL | Dog | 5 mg/kg/day, 13 weeks (Target organs: None identified) |
| | Rat | 5 mg/kg/day, 13 weeks (Target organs: Gastrointestinal System) |
| Stearic Acid (CAS 57-11-4) | | |
| <u>Acute</u> Inhalation | | |
| LC ₅₀ | Rat | > 0.16 mg/l/4h |
| Oral | | |
| LD ₅₀ | Rat | > 4600 mg/kg |
| Lactose Monohydrate (CAS 10039-26-6) <u>Acute</u> Oral LD ₅₀ | Rat | 29.7 g/kg |
| | Ναι | zə.i yiry |
| Skin corrosion/irritation Corrosivity | Prolonged skin co | ontact may cause temporary irritation. |
| Carprofen | Rabbit | Non-irritating |
| Serious eye damage/eye irritation Eye Contact | Direct contact wit | h eyes may cause temporary irritation. |
| Carprofen | Rabbit | Non-irritating |
| | | |



11. TOXICOLOGICAL INFORMATION

| Respiratory or skin sensitization Respiratory sensitization Skin sensitization Skin sensitization (GPMT) Carprofen | Not a respiratory sensitizer. May cause an allergic skin reactior experimental animals. However, w Carprofen Chewable Tablets have blotchy patches on their hands and Guinea Pig | orkers handling developed red and |
|--|---|--|
| Germ cell mutagenicity | No data available to indicate produpresent at greater than 0.1% are m | |
| Mutagenicity - Bacterial (Ames) | | |
| Carprofen | Salmonella | Negative |
| Mutagenicity - In Vivo Micronucleus | | |
| Carprofen | Mouse | Negative |
| Carcinogenicity | This product is not considered to b ACGIH, NTP, or OSHA. | e a carcinogen by IARC, |
| IARC Monographs. Overall Evaluation of Carcinogenicity | | Not listed |
| OSHA Specifically Regulated Substance | es (29 CFR 1910.1001-1050) | Not regulated. |
| US. National Toxicology Program (NTP) | Report on Carcinogens | Not listed. |
| Reproductive toxicity: | Suspected of damaging the unbor | n child. |
| Developmental effects | | |
| Carprofen | Rat | 20 mg/kg/day Embryo/ Fetal Development, Not Teratogenic Result: NOAEL |
| | Mouse | 40 mg/kg/day Prenatal & Postnatal Development, Not Teratogenic Result: NOAEL |



| 11. | TOXICOLOGICAL INFORMA | | | |
|-----|---|------------|-------------------------|---|
| | | | Rabbit | 6 mg/kg/day Prenatal & Postnatal Development, Embryotoxicity, Early embryonic development Result: NOAEL |
| | Reproductivity | , | | Organ: Oral |
| | • • | profen | Rat | 20 mg/kg/day Reproductive & Fertility, Fetotoxicity, Maternal toxicity Result: NOAEL |
| | Specific target organ toxicity - single exposure | Not classi | ified. | |
| | Specific target organ toxicity - repeated exposure Aspiration hazard | repeated | ingestion | ligestive system) through prolonged or |
| | Further Information | Anecdota | a potential for workers | handling Carprofen Tablets have to develop rashes upon exposure to dusts |

12. ECOLOGICAL INFORMATION

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Mobility in soil

No relevant studies identified.

Persistence/Degradability

No data is available on the degradability of this product.

Bioaccumulative Potential

No data available for this product. Not expected to bioaccumulate.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.



13. DISPOSAL INFORMATION

Disposal Instructions

Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations

Dispose of in accordance with applicable regulations.

Hazardous waste code

None known

Waste from residues / unused products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. TRANSPORTATION INFORMATION

DOT – Not regulated as dangerous goods

IATA – Not regulated as dangerous goods

IMDG – Not regulated as dangerous goods

Transport in bulk to Annex II of MARPOL 7/78 and the IBC Code - Not applicable



15. **REGULATORY INFORMATION**

US Federal Regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard – No

SARA 302 Extremely hazardous substance Not listed.

SARA 311/312 Hazardous chemical None

SARA 313 (TRI reporting) Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|----------------------|--|---------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | No |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |



15. **REGULATORY INFORMATION**

| United States and Puerto Ric | | |
|------------------------------|---|---------------------------|
| Country(s) or region | Inventory name | On inventory (yes/no)* |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |
| | | |

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

* A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory

16. OTHER INFORMATION

Legend

ACGIH: American Conference of Governmental Industrial Hygienists ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP) BOD: Biological Oxygen Demand CAS#: Chemical Abstracts Service Number ECHA: European Chemicals Agency FIFRA: Federal Insecticide, Fungicide and Rodenticide Act IARC: International Agency for Research on Cancer LC50: Lethal Concentration 50% LD50: Lethal Dose 50% N/A: Denotes no applicable information found or available NTP: National Toxicology Program OSHA: Occupational Safety and Health Administration PEL: Permissible Exposure Limit STEL: Short Term Exposure Limit TLV: Threshold Limit Value **TSCA:** Toxic Substance Control Act

Revision Date: April 14, 2022 Replaces: New document

Information Source and References

This SDS is prepared by Virbac Corporation based on information provided by internal and external references.

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